# Plantar Pressure and Shear Stress Reduction Insole for Diabetic Foot Ulceration

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## Background of the Invention

There are 16 million people or 5.9% of the population in the United States that have diabetes. Many people first become aware that they have diabetes when they develop one of its major complications such as blindness, heart disease, stroke, peripheral vascular disease, and numbness or neuropathy in the feet. High blood sugar level also affects the body immune system and cause delayed wound healing.

Diabetic foot complications are the most common cause of non-traumatic lower extremity amputations in the United States. The risk of lower extremity amputation is 15 to 46 times higher in diabetics than in normal persons, and the majority of diabetic foot complications begin with the formation of skin ulcers on the bottom of the foot.

One of the main causes for diabetic ulceration is the increase in plantar pressure on the bottom of the foot; especially, the forefoot and the heel area. Foot deformities, which are common in diabetic patients, lead to focal area of high pressure. When an abnormal focus of pressure is coupled with lack of sensation, a foot ulcer can develop. Therefore, off-loading plantar foot pressure is an important component in treating diabetic foot ulcerations.

## Description of Prior Art

There are many off-loading techniques and devices available, each having specific applications according to the anatomic location of the wound. Off-loading devices made for non-ambulatory use include airflow mattresses, soft padding for the bed and wheelchair, and heel protectors such as the multipodus boot that suspends the limb to completely remove pressure from the problem area.

For ambulatory patients with plantar foot ulcerations, the ultimate off-loading device is a total contact cast, which acts to transfer weight away from the foot and redistributes the forces of weight bearing proximally onto the leg. A removable cast walker device performs much of the same off-loading as a total contact cast but is often more easily tolerated by the patient because it is removable for bathing and for daily wound care. Other off-loading but less ideal devices include a half-shoe (or so-called "wedge shoe"), a postoperative/surgical shoe with soft accommodative padding layer. A randomized clinical study was conducted to compare the effectiveness of total-contact casts, removable cast walkers, and half-shoes to heal neuropathic foot ulcerations in individuals with diabetes. The study reports that a significantly higher proportion of patients were

healed in 12 weeks in the total contact cast group when compared with the two other modalities (89.5% vs. 65%, and 58.3%) (Off-loading the diabetic foot wound: a randomized clinical trial, Diabetes Care 2001 Nov;24(11):2016)

U.S. Pat. No. 5,197,942 (Brady) describes wearable foot orthoses with wound aperture to offload plantar pressure when a patient walk. However, most diabetic patients with foot ulceration have insensate foot and orthoses with hard material could create additional plantar foot ulceration.

U.S. Pat. No. 5,329,705 (Grim) describes removing grids of removable resilient hexagon elements in the insole to offload the plantar foot pressure. However, this practice will subsequently transferring peak plantar pressure to other part of the foot. Furthermore, as the pressure is reduced through the aperture (from removing the hexagon elements) it will put additional pressure around the wound edge and subsequently creating more skin undermining and calluses around the wound.

U.S. Pat. No. 5,483,757 (Frykberg) describes insole with preferably multiple evenly spaced holes extends through for breathing. These are limited number of small holes with the main purpose for air circulation through the insole. These hole design has no effective peak plantar pressure reduction.

U.S. Pat No. 5,797, 862, and 6,083,185 (Lamont) describes diabetic boot and insole consisting of an upper layer plastazote and lower layer of poron material which laminated together with additional metatarsal and scaphoid paddings to offload foot pressure. This kind of material is commercially available in sheets which can be cut out to fit into a shoe or boot. However, it still does not have the offloading capabilities such as the new invention (see testing below).

## Summary of the Invention

The main purpose of this invention is to develop a new insole design which can significantly reduce the plantar pressure under the forefoot and heel, and can be used as replacement insole for the diabetic shoe, diabetic healing shoe, and removable cast walker.

This new insole is consisting of shock absorbing and shear reducing composite layers of Poron or soft EVA for the bottom layer, Plastazote or cushioned polymer gel for the middle layer, and a closed cell Neoprene top cover. These materials are commercially available in sheets.

The main advantage and uniqueness of this invention, comparing to other existing insoles, are the evenly spaced holes throughout the insole. The holes will significantly reduce the direct plantar pressure and shear stress dynamically exerting on the plantar skin upon loading. When there is a focal point of pressure, the holes will be distorted or stretched to the direction of the pressure which will also allow the insole material to distorted or

"give" resulting in reduction of the peak plantar pressure and the associated shear stress. This will also eliminate any pressure transferring problems as encountered in other insoles. Removing the pressure will allow the insole material to return back to the original state.

Therefore, dynamic direct plantar pressure and shear stress can be significantly reduced by these holes.

This insole can also be used to offload plantar pressure of deformed foot which has bony prominences due plantar fat pads atrophy in people with rheumatoid arthritis.

This new insole, when used in conjunction with a shoe or with removable cast walker, will replace the total contact cast, which is the ultimate off-loading device for treating diabetic foot ulcerations.

**Brief Description of the Drawings**

Figure 1. is top view of the right insole

Figure 2. is a side elevation view of the right insole

Figure 3. is a cross sectional view of the right insole, taken along line A-A of Figure 1

Figure 4. is top view of the right insole, of interest area "A", showing non-loaded insole

Figure 5. is a top view of the right insole, of interest area "A", showing a loaded insole with focal pressure point

Figure 6. is a cross sectional view of the region of interest "A" upon loading, taken along line B-B

**Detailed Description**

This invention of the off-loading insole for diabetic ulceration consists of a shock absorbing composite layers insole, which also has additional capability to reduce the peak plantar foot pressure and shear stress on the plantar skin by evenly spaced holes through the insole. See Figure 1, 2, 3.

The insole main shape can be of a foot, existing shoe insole, or the outline of a post surgical shoe or removable cast walker.

The bottom layer material is soft EVA with a thickness of 1/4" to 1/2" which has excellent shock absorption, high direct impact performance, and high resiliency.

The middle layer material can be either pink Plastazote, or cushioned polymer gel with a thickness of 1/4" to 3/8" to mainly absorb the direct plantar pressure and to reduce the shearing stress.

The top layer material is closed cell Neoprene with a thickness of 1/8" and is used as the top cover for the insole.

All three materials are glued together to form a composite layered insole which is 1/2" to 1" thick. These materials are commercially available. See Figure 2.

Main shear stress reduction is accomplished by the middle layer since it has the elastic property to "slide" or "give" between the top and bottom layers when the direction of force is parallel or near parallel to the insole surface.

Additional plantar pressure and shear stress reduction are accomplished by evenly spaced holes drilled or punched through all layers of the insole. These holes, can be varied in sizes and shapes to accommodate different weight loading requirements, and are separated by at least 1/4" to 1" away from each others.

Figure 4 shows shape of the holes when in a relaxed or non-loaded position.

Figure 5 and 6 show that when there is a focal point of pressure, the holes will be distorted or stretched to the direction of the pressure which will also allow the insole material to distorted or "give" resulting in reduction of the peak plantar pressure and the associated shear stress. Removing the pressure will allow the insole material to return back to the original state. Therefore, additional dynamic direct plantar pressure and shear stress can be significantly reduced by these holes.